

HOSPIRA, INC. and ORION
CORPORATION,

Plaintiffs,

v.

SANDOZ INTERNATIONAL GmbH,
SANDOZ INC., and SANDOZ CANADA
INC.,

Defendants.

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

CIVIL ACTION No. 3:09-cv-04591 (MLC/TJB)

REDACTED VERSION

**PLAINTIFFS' RESPONSIVE BRIEF IN SUPPORT OF THEIR REQUEST TO
PRECLUDE SANDOZ INC.'S AND SANDOZ CANADA'S PROPOSED INVALIDITY
AND NON-INFRINGEMENT CONTENTIONS**

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I. PRELIMINARY STATEMENT

Plaintiffs Hospira, Inc. and Orion Corporation (“Plaintiffs”) submit this responsive brief in support of their request to preclude new invalidity and non-infringement contentions that were proposed by Sandoz Inc. and Sandoz Canada (“Defendants”).

Stripping away the attorney argument, the facts recited in Defendants’ brief expose a pattern of conduct that evinces a disregard for the Court’s deadlines and the Local Patent Rules. It is now clear that Defendants, including Sandoz Canada, put little to no effort into exploring and developing their invalidity theories prior to the deadline for disclosure of contentions. Immediately after the deadline, Defendants apparently began to revise their invalidity contentions by performing searches and developing analyses in January that undoubtedly could have been performed prior to the December deadline. After finding what they now contend is important, case-dispositive prior art, Defendants sat silent for another seven months. Throughout that entire time, Plaintiffs relied on Defendants’ December 2009 contentions to focus their case, and the parties engaged in a six-month *Markman* process based on those contentions. Then, days after *Markman* briefing was completed, Defendants attempted to serve new contentions. Plaintiffs respectfully ask the Court to preclude these new contentions for at least three reasons.

First, Sandoz Canada will not be denied “due process” if it cannot serve new contentions because it is not being denied the opportunity or ability to defend itself in this case. Rather, Sandoz Canada would be held to the defenses that (a) it would have made when this case started if Defendants had not engaged in [REDACTED] and (b) Sandoz Inc. made in its stead. In short, Sandoz Canada is not asking for an opportunity to present arguments that are specific to Sandoz Canada, but instead for an opportunity for its attorneys to present arguments that those same attorneys have no good cause to present on behalf of Sandoz Inc. Defendants’ opportunistic efforts to use Sandoz Canada’s addition to the case to

revise their contentions based on information they and their counsel knew or should have known more than seven months ago should be rejected.

Second, Defendants have not shown the level of diligence that is required by L. Pat. R. 3.7 and this Court's January 6, 2010 Scheduling Order (D.I. 23, Section 6). Defendants have not provided *any* description of their actions prior to serving their December 2009 contentions, let alone demonstrated that they conducted a "diligent search" at that time. They also admit that most of the additional references were located in January 2010, and thus those references are not "recently discovered." Defendants provide no good cause for the late discovery of those references, and nothing happened in the interim to cause that delay—Plaintiffs' contentions were not served until over a month later, and Defendants had not yet even requested documents from Plaintiffs at that time. [REDACTED]

Third, the prejudice to Plaintiffs caused by the delay in claim construction will far outweigh any alleged prejudice to Defendants. Defendants' new contentions require construction of at least two additional claim terms based on a reference that Defendants had in January 2010, and should have had well before they served contentions in December 2009. This shift of positions halfway through the 30-month stay will require the parties and the Court to spend more time, energy, and money, and could impact the Court's ability to hold a trial and reach a decision before expiration of the 30-month stay.

II. SANDOZ CANADA IS NOT BEING DENIED DUE PROCESS.

Defendant Sandoz Canada can and should defend itself based on the contentions submitted by its attorneys in December 2009 on behalf of Sandoz Inc., which presumably contained the most complete description of invalidity and noninfringement positions available to any of the Defendants at that time. The "due process" concerns raised by Sandoz Canada are a

red herring that misdirects attention away from the main issue—that Defendants have not acted with diligence, and any prejudice to them is caused by their own inaction.

Sandoz Canada has not identified any argument that it would have raised in December 2009 that it is precluded from making now. Sandoz Canada cannot do so because it would not have done anything differently—if Sandoz Canada had been a party in December, it would have filed the exact same contentions as Sandoz Inc. For example, if Sandoz Canada was aware of Talke 1995 or any of the other new references in December 2009, but was denied an opportunity to provide contentions based on those references, Sandoz Canada’s protestations of denial of due process might ring true. Instead, they ring hollow because any information and analysis Sandoz Canada was aware of was incorporated into Sandoz Inc.’s invalidity contentions through lawyers that were representing both Sandoz Inc. and Sandoz Canada.

If Sandoz Canada’s due process argument had any merit, it would be with respect to infringement. However, its noninfringement contentions related to the ANDA product and administration thereof are substantively identical to those of Sandoz Inc. [REDACTED]

[REDACTED] At most, Sandoz Canada should be able to add noninfringement contentions that are specific to its own [REDACTED]

Defendants also contend that Sandoz Canada should be able to add new contentions because of the alleged delay in adding it as a party. (Def.’s Br. 3-4.)¹ [REDACTED]

¹ References to “Def.’s Br.” refer to the Memorandum of Law In Support Of Sandoz Canada Inc.’s Right To Serve Invalidity And Non-Infringement Contentions And Sandoz Inc.’s Motion For Leave To Amend Its Preliminary Invalidity And Non-Infringement Contentions, dated Sept. 10, 2010.

[REDACTED] any delay in adding Sandoz Canada is irrelevant for two reasons. First, Plaintiffs added Sandoz Canada by the April 23 deadline to add parties and thus did not violate this Court's Scheduling Order or the Local Patent Rules, as Defendants have done. Second, it was Sandoz Canada's insistence on Hague service, and on taking the maximum time to answer, that delayed its official entry into the case during the exact time that the parties were engaging in the *Markman* process.²

In short, the December 2009 contentions were filed by Sandoz Canada's counsel; [REDACTED]

[REDACTED] and they were based on information that was known or should have been known to Sandoz Canada as easily as to Sandoz Inc. Thus, even if Sandoz Canada had been a party in December, Defendants' Counsel would not have done anything differently if they had been wearing their "Sandoz Canada" hats in addition to their "Sandoz Inc." hats back in December 2009. Even today, Defendants contentions admittedly "mirror" each other. That is because they have the same lawyers and the same legal interests in this ANDA litigation.

Thus, Sandoz Canada will have just as much opportunity to defend its interests in this case as Sandoz Inc. has. Plaintiffs have never objected to Sandoz Canada adopting Sandoz Inc.'s original contentions and defending its interests along with Sandoz Inc. Plaintiffs only ask that both Defendants be held to the arguments their lawyers submitted in December 2009, in accordance with the Local Patent Rules and this Court's Scheduling Order.

III. DEFENDANTS HAVE NOT SHOWN DILIGENCE.

In order to show good cause to serve new contentions, Defendants have the burden of establishing diligence. *See O2 Micro.*, 467 F.3d at 1366.³ They have failed to meet that burden for two reasons: (1) they have not demonstrated that they conducted a diligent search prior to serving their original contentions; and (2) they have not shown that they acted diligently after learning of the additional references.

A. Defendants Have Not Shown Diligence Prior To December 2009.

Defendants have provided no explanation for their failure to identify most of the additional references prior to serving their December 2009 contentions. [REDACTED]

[REDACTED]

Defendants say they only learned of some references, such as Easson, when they saw them in the Savola Thesis. (Def.'s Br. 19.) However, Easson is cited in Savola 1991, which is cited in the Notice Letter. (*See* 9/22/10 Antonian Cert., Ex. C at 198.)⁴

Moreover, the Savola Thesis is a publicly available review of other published literature that was known or should have been known by December 2009 at the latest. The Savola Thesis states that it "is based on" seven other papers co-authored by Savola. (*See* 9/22/10 Antonian Cert., Ex. D at ORN-PRECEDEX 00018091 ("This thesis is based on the following papers cited in the text by their Roman numerals.")) Most if not all of those papers were available in July 2009 and were cited in Savola 1991 or in the Savola 1986 reference that was cited in Savola

³ Federal Circuit law applies to this issue because "local patent rules on amendment of infringement contentions are unique to patent cases and have a close relationship to enforcement of substantive patent law." *O2 Micro*, 467 F.3d at 1364-65.

⁴ Indeed, Defendants could have more easily identified Easson from Savola 1991 (which only has 37 citations) than from the Savola Thesis (which has hundreds of citations).



1991. (*Compare* 9/22/10 Antonian Cert., Ex. D, Savola Thesis at ORN-PRECEDEX 00018091 with Ex. C, Savola 1991 at 198 and Ex. E, Savola 1986 at 283.)

Defendants do not explain what search they conducted in January 2010, if any, that could not have been conducted prior to or between July and December 2009. Defendants thus have not met their burden of showing that these references are recently discovered “despite earlier diligent search” as specified in L. Pat. R. 3.7(b).



Defendants may claim that their late discovery of the references was inadvertent. However, that is not sufficient to satisfy the Local Patent Rules because “an inadvertent omission does not establish diligence.” *See West v. Jewelry Innovations, Inc.*, C 07-1812 JF (HRL), 2008 U.S. Dist. LEXIS 84928, at *10-11 (N.D. Cal. Oct. 8, 2008) (“[I]nadvertence is hardly the same as diligence. As this District has explained, carelessness is not compatible with a finding of diligence and offers no reason for a grant of relief.”) (internal quotation marks omitted).

B. Defendants Have Not Shown Diligence From January To August 2010.

Even if the discovery of numerous references in January 2010 (Def.’s Br. 19; 
) can somehow be justified, Defendants do not adequately explain why they waited another *seven months* to amend their contentions. *See O2 Micro*, 467 F.3d at 1367 (affirming that a party lacked diligence when it waited three months to amend its contentions after learning of a new theory at a deposition).

To meet their burden of establishing diligence, Defendants must provide a detailed explanation of (a) what they were doing during the delay and (b) how those activities related to the new contentions. The Federal Circuit has rejected arguments that a party needed time to

“digest and marshal [the] evidence” or that its “lawyers were busy with discovery during the delay period.” *Id.* (alteration in original). Here, Defendants’ excuses are similarly inadequate.

From January to April 2010, Defendants say that they “continued to evaluate the relevance of these newly-discovered prior art references” as they “began reviewing Plaintiffs’ initial waves of document production.” (Def.’s Br. 19.) But being “busy with discovery” is not a valid excuse for a lack of diligence. *O2 Micro*, 467 F.3d at 1367.

[REDACTED]

Defendants thus knew of the alleged materiality of numerous references, including the Talke 1995 reference that requires additional claim construction. [REDACTED]

If the additional references are as important as Defendants now say they are, then Defendants have no excuse for waiting to seek leave to amend their contentions. *See CBS Interactive, Inc. v. Etilize, Inc.*, 257 F.R.D. 195, 202 (N.D. Cal 2009) (rejecting a party’s motion to amend contentions where the party “obviously believed it was aware of sufficient details regarding [the newly added] technology to plead allegations of inequitable conduct and *Walker Process* fraud in this action several months ago”).

From May to August 2010, Defendants do not even purport to describe any diligent activity. Defendants merely decided to wait for Sandoz Canada to serve its contentions before Sandoz Inc. would amend its contentions. Defendants made the unilateral decision—not discussed with Plaintiffs or the Court—that Sandoz Inc. could “follow a similar schedule for amending its contentions and/or joining those to be served by Sandoz Canada as of right.” (Def.’s Br. 21.) Thus, Defendants apparently believed in May that a new schedule for contentions was necessary, but did not even propose any such schedule until the end of July.

(Def.'s Br. 5.) Moreover, Sandoz Inc. was apparently preparing to serve new contentions whether or not Sandoz Canada was added to the case, but elected not to do so until substantive *Markman* briefing was concluded.

In sum, Defendants have not proven diligence before serving their original contentions in December 2009 or after learning of additional references in January 2010, and thus have not shown good cause to serve new contentions.

IV. DEFENDANTS' NEW CONTENTIONS PREJUDICE PLAINTIFFS.

Because Defendants have failed to establish good cause, the Court can preclude Defendants from serving new contentions without considering the prejudice to Plaintiffs. *See O2 Micro*, 467 F.3d at 1368 ("Having concluded that the district court could properly conclude that O2 Micro did not act diligently in moving to amend its infringement contentions, we see no need to consider the question of prejudice to MPS.").

If the Court does consider prejudice, however, the undue prejudice to Plaintiffs caused by delaying the claim construction process outweighs any alleged prejudice to Defendants.

Defendants' new contentions will require the construction of at least two additional claim terms.

[REDACTED] not only will Plaintiffs and the Court be forced to engage in a second *Markman* process, but the claim construction delay will cause the parties to conduct all of fact discovery—and most or all of expert discovery—using alternative claim constructions. Such a burdensome and inefficient result defeats the purpose of the Local Patent Rules and provides sufficient basis to deny Defendants' new contentions. *See Sybase, Inc. v. Vertica Sys. Inc.*, Case No. 6:08 CV 24, 2009 U.S. Dist. LEXIS 110775, at *6 (E.D. Tex. Nov. 30, 2009) (denying party's ability to amend contentions after claim construction briefing and the *Markman* hearing were completed).

Defendants assert that they will be prejudiced if they are precluded from asserting new substantive arguments. However, the purpose of the Local Patent Rules is to prevent parties from shifting their theories and making new substantive arguments whenever they want. Courts often make procedural decisions that affect a party's substantive case, but that is the natural result of enforcing the rules. Indeed, the Federal Circuit has recognized that local patent rules like the ones in this District "are likely to directly affect the substantive patent law theories that may be presented at trial." *O2 Micro*, 467 F.3d at 1364; *see also King Pharm., Inc. v. Sandoz, Inc.*, Civil Action No. 08-5974 (GEB/DEA), 2010 U.S. Dist. LEXIS 50163, at *9 (D.N.J. May 19, 2010) (denying Sandoz Inc. leave to add a reference to its contentions despite Sandoz Inc.'s assertion that it was the only cited prior art that expressly disclosed one element of the claims).

In this case, any prejudice to Defendants is of their own making. Defendants knew of allegedly material references for months before they attempted to amend their contentions and well in advance of the claim construction deadlines, [REDACTED]

[REDACTED]

In addition, any prejudice will be minimal at best because many of the additional references are not recently discovered "material prior art" as required by the Local Patent Rules.⁵

[REDACTED] In addition, other references are cumulative of information that Defendants knew or should have known before December 2009. For example, the Savola Thesis is a review article that cites prior publications without adding new information. The information in the Savola Thesis is cumulative of at least the '664 Patent and other Savola references that Defendants knew or should have known of in [REDACTED] 9/22/10 Antonian Cert. Ex. D, Savola Thesis at ORN-PRECEDEX 00018091.)

In short, Defendants will not be prejudiced if they are precluded from making new substantive arguments and, even if they were, any prejudice is of their own making and is outweighed by the prejudice to Plaintiffs.

V. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court preclude Defendants' from serving their proposed contentions.

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